Medical Material Quality Control Message MMQC-24-1057

Message Number: MMQC-24-1057

Released On: 04-Sep-24
Message Class: Informational
Material Type: Vaccine

MMQC\MMI Reference: FDA Recall Reference: ECRI Reference: DLA Reference: MFG Release Date:

Subject:

2024-2025 Pfizer COVID-19 mRNA vaccines Ordering Guidance

Reason / Information:

The US Army Medical Materiel Agency Distribution Operations Center (USAMMA DOC) in conjunction with Defense Health Agency Medical Logistics (DHA MEDLOG) are providing ordering guidance for 2024-2025 Pfizer COVID-19 mRNA vaccine. REASON: On 22 August 2024, the U.S. Food and Drug Administration approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. The updated mRNA COVID-19 vaccine includes Comirnaty, licensed by the FDA, which is approved for individuals 12 years of age and older.

Disposition / Instructions:

ACTIONS NEEDED:

1) Medical Treatment Facilities (MTFs) and vaccination sites can begin submitting orders through Pharmacy Prime Vendor (PPV) program with Cencora, (formerly known as AmerisourceBergen) for the 2024-2025 Pfizer COVID-19 mRNA vaccine using their normal Defense Logistics Medical Standard Support (DMLSS)/Theater Enterprise-Wide Logistics System (TEWLS) ordering

process for prime vendor (PV) ordering by setting the source of supply (SOS) to PVP for any of the national drug codes (NDC) listed below. Below are some ordering reminders:

----- COVID-19 Vaccines are no longer free issued item. Coordinate with your financial team to ensure funding is available for the purchasing of the vaccine.

----- MTFs submitting COVID orders within FY25 should tag all 2024-2025 COVID-19

vaccine purchases with FCA Code 4873.

- ----- COVID-19 vaccines will not be tracked within the DMLSS Assemblage Management module.
- 2) CONUS PVP Customers, when ordering/receiving COVID-19 vaccines remember the following:
- ----- Comirnaty, which will ship at refrigerated temp of 2C-8C with an extended shelf-life as indicated on the manufacturer/FDA label.
- ----- Pediatric and Infant vaccine will ship at refrigerated temp of 2C-8C with the resulting reduced shelf-life as indicated on the By Use Date (BUD) Label that the PVP will adhere to the material.
- 3) OCONUS PVP Customers when ordering/receiving COVID-19 vaccines remember the following:

Comirnaty, Never Frozen (NF), Never Frozen (NF) Vaccine is not currently available, pending development of the required distribution lanes. An MMQC will follow and provide updates when this vaccine is available for ordering. When available to order there will be a minimum ordering quantity of 150 doses (15 packages). Consider ordering Spikevax or Novavax, once available, to cover the 12 years and older population until the required distribution lanes for Comirnaty are established.

- ----- PVP will be using their standard FedEx Priority Alert contract and transit times. Product will initially be staged at a centralized PVP DC, and then moved to the standard Cencora Sacramento (PACOM) and Cencora Bethlehem (EUCOM) DCs, with a By Use Date (BUD) label affixed to the material reflecting a reduced shelf life (initiated at 2-8C repackaging). ----- PACOM will be shipping on Fridays only and EUCOM will be shipping on Mondays only.
- ----- Material will ship in DLA's (PVP's) standard refrigerated (2-8C) shipper, to include an Orange-labeled Sensitech TempTale.
- ----- Customers will follow the same standard receiving process as all other Pharm PV CCM shipments.
- ----- It is estimated that DLA Troop Support Cold Chain will continue to send pre-alert emails for this next year; after that, customers will receive the PV's standard automated shipping alerts.
- 3) Navy Fleet assets will order by placing MilStrip orders directly with DLA to utilize the Direct Vendor Delivery (DVD) program, as currently done for all other non-DLA depot stocked vaccines. The Fleet Prime Vendor program will not support COVID vaccine requirements.
- 4) Non-Pharm PV customers will be expected to order through their Theater Lead Agent for Medical Materiel (TLAMM), which is the standard SOS for most vaccines, or they may also utilize the DLA DVD program.
- 5) MTFs with questions or concerns related to the DLA Cold Chain program and/or product quality should continue to contact the DLA Troop Support Cold Chain program office, per the terms of the PVP contract. Any questions or concerns related to the PVP program and/or product availability/information should continue to contact their Cencora DoD Customer Care Representative.
- 6) National Stock Numbers are being generated for the DLA DVD Program. However, MTFs should submit PVP orders using the National Drug Codes (NDCs) listed below:

NSN (FSC-NIIN): 6505 - NS3

Local NSN: -

NDC: 00069-2432-10

Nomenclature: COMIRNATY 2024-25(12Y UP) SYRG 0.3ML

UI: CA Manufacturer: PFIZER

Distributor:

LOT / SN:

All

NOTE 1:

OCONUS SITES: Comirnaty, Never Frozen (NF), Vaccine is not available currently until the transportation lane is confirmed.

NSN (FSC-NIIN): 6505 - NS4

Local NSN: -

NDC: 59267-4438-02

Nomenclature: PFIZER COVID 2024-25(5-11Y)EUA 0.3ML

UI: CA Manufacturer: PFIZER

Distributor:

LOT / SN:

All

NSN (FSC-NIIN): 6505 - NS5

Local NSN: -

NDC: 59267-4426-02

Nomenclature: PFIZER COVID 2024-25(6M-4Y)EUA 0.9ML

UI: CA Manufacturer: PFIZER

Distributor:

LOT / SN:

All

Service/Additional Instructions:

POC Contact Information:

Army (USAMMA DOC Vaccines)

Email: usarmy.detrick.usamma.mbx.vaccines@army.mil

Phone (COMM): 301-619-4318 **Phone (DSN):** 343-4318 **Fax:** 301-619-4468

DHA MEDLOG Vaccine

Email: dha.jbsa.med-log.mbx.vaccine-manager-group@health.mil

Phone (COMM): 301-619-8849 **Phone (DSN):** 343-8849

Fax:

NAVY FLEET

Email: usn.detrick.nmrlc-detftdmd.list.vialhelp@health.mil

Phone (COMM): 301-619-8054 **Phone (DSN):** 343-8054 **Fax:** 301-619-2473

US AIR FORCE

Email: usaf.detrick.afmoa.mbx.sgmp-scs-alerts@health.mil

Phone (COMM): 301-619-4183 **Phone (DSN):** 343-4183 **Fax:** 301-619-2557

USAMMC-E Pharmacy

Email: usarmy.rheinland-pfalz.amlc.list.usammce-pharmacy-consultant@mail.mil

Phone (COMM): 49-6331-86-7230

Phone (DSN): 495-7230

Fax:

USAMMC-K

Email: usarmy.carroll.usammc-k.list.usammc-k-customer-support@mail.mil

Phone (COMM): 05033374490/+821092328897

Phone (DSN): 315-737-4490

Fax:

USCG

Email: D05-DG-HSWLSC-USCG-Pharmacy-Logs@uscg.mil

Phone (COMM): 757-628-4331

Phone (DSN):

Fax:

Additional Message Recipients:

Please ensure dissemination of this information to the following:

Command Channels

Immunization Clinics

Medical Log Officers

Medical Maintenance

Medical Staff

Pharmacy Officers

Supply Officers

Supported Activities/Centers

Vaccince Shot Teams

Message Dissemination Authorization

COMNAVSURFPAC/COMNAVSURFLANT INSTRUCTION 6000.1. SECTION 12. Procedures for Quality Control Surveillance of the Medical Material, g. The SMDR and

Pharmacy technician shall subscribe to MMQC messages to ensure all drug recall, extensions and suspensions are addressed in an expeditious manner.

AF Activities will take action as prescribed in AFMAN41-209, Medical Logistics Support, Chapter 7. For MAJCOMS & NGB – This Msg has been transmitted to all designated subordinate medical activities

See Army Regulation (AR) 40-61, 28 January 2005, Chapter 4, and The Department Of The Army Supply Bulletin (SB 8-75-11) For Applicable Policies and Procedures.

DODD 5105.22 and DODD 6025.13

*** END OF MESSAGE ***